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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,275	10/08/2003	Hans Jochen Lang	DEAV1996/F140US	6888

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EXAMINER

WILLIAMS, LEONARD M

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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03/27/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/680,275	Applicant(s) LANG ET AL.	
	Examiner LEONARD M. WILLIAMS	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18 and 20-38 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-18 and 20-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) ☐ Other: ____. |

Detailed Action

Examiners Note

The examiner respectfully points out that the applicant's have not pointed out what claims have been amended in the remarks section of the amendments. The examiner reminds applicant that that they must specifically point what claims have been amended. This is especially important in cases where the claims are 266 pages long. The examiner finds that only claim 17 seems to be amended by deleting "or preventing" from the claim.

The examiner also reminds applicant that the species elected in the restriction requirement of 04/30/2007 was 4-isopropyl-3-methylsulfonylbenzoylguanidine.

Response to Amendment/Arguments

The amendment received 01/08/2008 amending claim 17 and cancelling claims 19 and 39-44 has been entered.

The amendment of claim 17 is sufficient to overcome the 112-1st rejection of the last office action and thus said rejection is withdrawn.

The cancelling of claims 39-44 necessitates the withdrawal of the 103(a) rejection over those claims.

Claims 17-18 and 20-38 are presently pending.

Applicant's arguments filed 01/08/2008 have been fully considered but they are not persuasive.

The applicant's assert on page 267 of the remarks that "concluding that treating patients with angina pectoris could be used to treat patients with raised lipid levels is confusing cause and effect" the examiner respectfully disagrees and the parsing of specifics from the Robbins reference to obfuscate the broader issue of ischemic heart disease and its relation to raised lipid levels amounts to piecemeal attacking of the references. Robbins clearly teaches that hyperlipidemia is a **major** risk factor in atherosclerosis. Robbins further teaches there is a connection between atherosclerosis with ischemic heart disease (including myocardial infarction and angina pectoris). That arrhythmias can be a causal and/or effect of IHD. Englert teaches the compounds claimed as being cardio protective and useful in the treatment of arrhythmias and angina pectoris. It would be obvious to use Englert's compounds in methods of cardioprotection and treatment of arrhythmias and angina pectoris and it is an inherent property of the compounds to lower lipid levels. Hyperlipidemia is a major risk factor in atherosclerosis and IHD.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. " A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are

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necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new **use**, new **function** or **unknown property which is inherently present** in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

As applicant's amendment to claim 17 does not change the reasons for the rejection of the claim as written, the 103(a) rejection of 17-18 and 20-38 is maintained and reproduced below. This action is made **final**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-18 and 20-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Englert et al. (US patent No. 5091394) in view of Robbins Pathologic Basis of Disease (5th ed., pp. 473-476, 519-521, 528-529, and 537-539).

Englert et al. teach, in col. 1 line 5 to col. 2 line 65, benzoylguanidines of formula I (encompassing the presently elected species) as cardioprotective compounds useful in the treatment of arrhythmias and angina pectoris.

Englert et al. do not teach a method of treating or preventing raised blood lipid levels by administration, to a patient in need of such, of a compound of formula I.

Robbins teaches, on page 473, that atherosclerosis is a disease primarily of the elastic arteries consisting of a raised focal plaque within the intima, having a core of lipid (mainly cholesterol and cholesterol esters) and a covering fibrous cap. Robbins

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teaches, on pages 474-476, that hyperlipidemia (hypercholesterolemia and other abnormalities) is a major risk factor in atherosclerosis. Other major risk factors include hypertension and diabetes. Robbins teaches, on pages 519-521, that there are five mechanisms by which dysfunction of the heart or the overall cardiovascular system can occur: 1) disruption of the continuity of the circulatory system (gunshot wound); 2) disorders of cardiac conduction or arrhythmias; 3) a lesion preventing valve opening or one narrowing the lumen of a vessel which obstructs blood flow; 4) regurgitant flow and 5) failure of the pump itself. On page 521, figure 12-1, the interconnection of hypertension, valvular disease and/or myocardial infarction with hypertrophy and/or dilataion and subsequent congestive heart failure, arrhythmias, and/or neuronal stimulation is shown. Robbins teaches, on pages 528-529, that myocardial infarction is the most important form of ischemic heart disease (IHD-also includes angina pectoris) in industrialized countries and that the incidence and major risk factors are the same for atherosclerosis. Thus smoking, hypertension, hypercholesterolemia and diabetes mellitus (and other causes of hyperlipoproteinemia) are the major risk factors in the development of ischemic heart disease and myocardial infarction. Robbins teaches, on pages 537-539, that the consequences and complications of myocardial infarction include cardiac arrhythmias, pulmonary edema, and thromboembolism.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Englert et al. compounds of formula I (encompassing the presently claimed species) in a method of treating or preventing raised blood lipid levels, as the methods of Englert et al. of treating angina pectoris and/or arrhythmias to

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patients in need thereof would have significant overlap with the patients as presently claimed as Robbins clearly indicates the association of atherosclerosis (and its risk factors of hypertension, diabetes, hypercholesterolemia etc...) with ischemic heart disease (IHD-angina pectoris, myocardial infarction, etc..). Further Robbins clearly indicates that arrhythmias are intimately associated with IHD and can be both a causal factor and a result of IHD. One would be motivated to use the compounds of Englert et al. as they encompass the presently claimed compounds and have already been demonstrated as safe and effective in the treatment of arrhythmias and angina pectoris.

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD M. WILLIAMS whose telephone number is (571)272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617